



Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.

Introduction

The purpose of this position statement by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling in the surgical management of stress urinary incontinence, the type of urine leakage generally associated with coughing, laughing and sneezing.

Developed in the early 1990's, midurethral slings (MUS) treat stress urinary incontinence (SUI) in a minimally invasive, generally outpatient procedure. This technique utilizes a small mesh strip composed of monofilament polypropylene placed through the vagina under the mid-urethra exiting from 2 small sites in either the suprapubic or groin areas.

SUI is a highly prevalent condition of involuntary urine leakage resulting from faulty closure of the urethra typically associated with coughing, sneezing or exertion. SUI is often a debilitating and bothersome condition that can substantially reduce a woman's quality of life. Although non-surgical treatments such as pelvic floor exercises and behavioral modification are helpful in alleviating symptoms in some women [1], many proceed with surgery which is a more effective treatment [2].

In July 2011, the U.S. Food and Drug Administration (FDA) released a white paper [3] and safety communication [4] on the safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. In addition, lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI. This negative perception of the MUS is not shared by the medical community and the overwhelming majority of women who have been satisfied with their MUS. Furthermore, the FDA website states that: "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year." [5].

EXHIBIT

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Justification for the Position Statement

1. Polypropylene material is safe and effective as a surgical implant.

Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. [6, 7] As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years [8].

2. The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history.

A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI [9]. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature [9]. The MUS has been studied in virtually all types of patients, with and without comorbidities, and all types of SUI. Multiple randomized, controlled trials comparing types of MUS procedures, as well as comparing the MUS to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness [9-12] and patient satisfaction [12]. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy [8]. No other surgical treatment for SUI before or since has been subject to such extensive investigation.

3. Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.

Since the publication of numerous level one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There have been over 100 surgical procedures developed for the management of SUI and there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to historic options that have been used to treat SUI over the past century. Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard for stress incontinence surgery [13]. Over 3 million MUS have been placed worldwide and a recent survey indicates that these procedures are used by > 99% of AUGS members [14].

4. The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI.

The midurethral sling was not the subject of the 2011 FDA Safety Communication, "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse." [3]. In this document, it was explicitly stated: "The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date." In 2013, the FDA website stated clearly that: "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year." [5].

Conclusion

The polypropylene-midurethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percent of incontinent women to live without treatment. One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence.

Our Organizations

The American Urogynecologic Society (AUGS), founded in 1979, is the premier non-profit organization representing more than 1,700 members including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, as well as researchers from many disciplines, all dedicated to treating female pelvic floor disorders (pelvic organ prolapse and urinary incontinence). As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS promotes the highest quality patient care through excellence in education, research and advocacy.

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is a non-profit organization dedicated to improving the art and science of Urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology and pelvic floor dysfunction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals, and has grown to over 500 members.

Midurethral Sling Task Force

This position statement was drafted by members Charles Nager, Paul Tulikangas, and Dennis Miller from AUGS and Eric Rovner and Howard Goldman from SUFU.

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References

1. Imamura, M., et al., *Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence*. Health Technol Assess, 2010. **14**(40): p. 1-188, iii-iv.
2. Labrie, J., et al., *Surgery versus physiotherapy for stress urinary incontinence*. N Engl J Med, 2013. **369**(12): p. 1124-33.
3. FDA, *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse*. 2011: <http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/UCM262760.pdf>.
4. FDA, *FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse* <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>. 2011.
5. FDA, *Considerations about Surgical Mesh for SUI* <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm>. . 2013.
6. Cobb, W.S., K.W. Kercher, and B.T. Heniford, *The argument for lightweight polypropylene mesh in hernia repair*. Surg Innov, 2005. **12**(1): p. 63-9.
7. Scott, N.W., et al., *Open mesh versus non-mesh for repair of femoral and inguinal hernia*. Cochrane Database Syst Rev, 2002(4): p. CD002197.
8. Nilsson, C.G., et al., *Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence*. Int Urogynecol J, 2013. **24**(8): p. 1265-9.
9. Ogah, J., J.D. Cody, and L. Rogerson, *Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women*. Cochrane Database Syst Rev, 2009(4): p. CD006375.
10. Novara, G., et al., *Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence*. Eur Urol, 2010. **58**(2): p. 218-38.
11. Ward, K. and P. Hilton, *Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence*. BMJ, 2002. **325**(7355): p. 67.
12. Richter, H.E., et al., *Retropubic versus transobturator midurethral slings for stress incontinence*. N Engl J Med, 2010. **362**(22): p. 2066-76.
13. Cox, A., S. Herschorn, and L. Lee, *Surgical management of female SUI: is there a gold standard?* Nat Rev Urol, 2013. **10**(2): p. 78-89.
14. Clemons, J.L., et al., *Impact of the 2011 FDA transvaginal mesh safety update on AUGS members' use of synthetic mesh and biologic grafts in pelvic reconstructive surgery*. Female Pelvic Med Reconstr Surg, 2013. **19**(4): p. 191-8.